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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,870	02/15/2000	Charles S. Vann	0550-0076.30	6464

22896 7590 01/06/2004

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	25

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

AS-25

Office Action Summary	Application No.	Applicant(s)	
	09/506,870	VANN ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 48-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-2, 4-7, 11-15, 17-19, 21, 24-25, 55* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *3,8-10,16,20,22,23,48-54 and 56-62* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. In view of the supplemental appeal brief filed on September 09, 2003, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 24, 25, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is intended to further limit "said substrate" the substrate is not considered as an element of the invention for it is not positive recited as an element of the system.

As to claims 25 and 55 it is unclear what is meant by the limitation of "field of view". Is the field of view for the operator or technician?

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

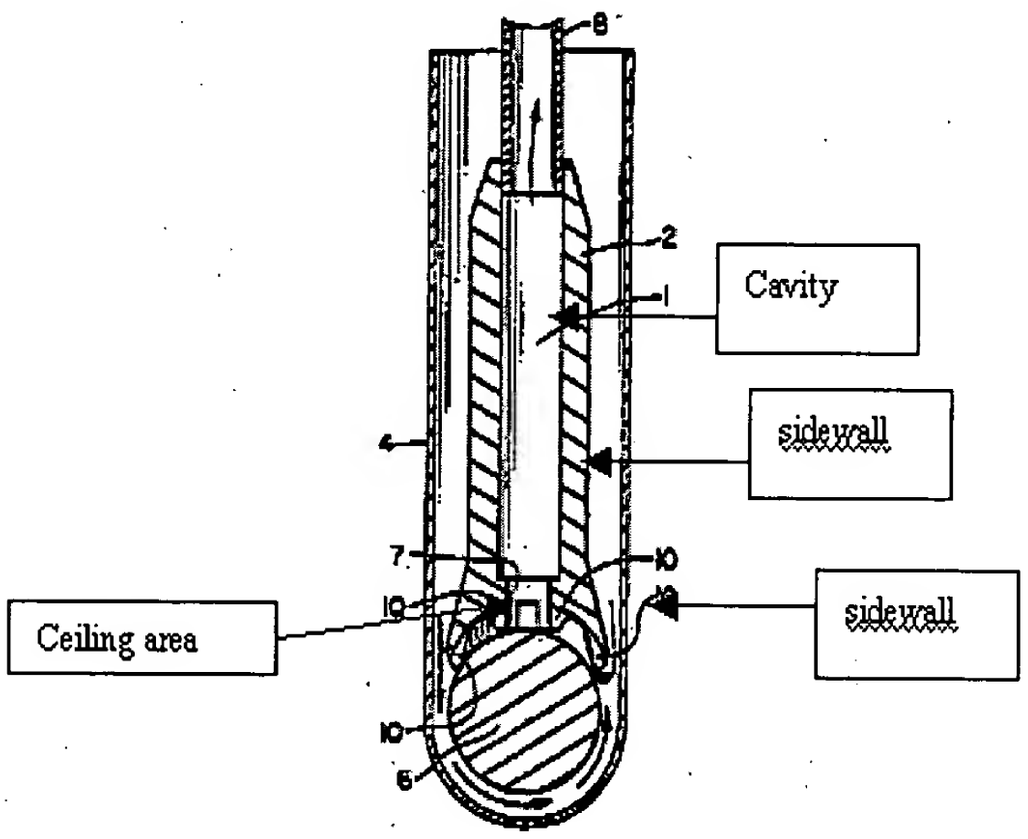
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4-7, 11, 15, 17-19, 21, 24-25, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wells US 5,185,269 in view of Elliot et al. US 5,935,859.

Wells discloses an immunobead aspirator reduces the amount of carry over liquid which remains within a test tube or other immunoassay vessel after an aspiration procedure. When the immunobead aspirator lifts up the immunobead during the aspiration procedure, the immunobead contacts an array of protuberances within an inverted bowl from which a vacuum is drawn. The array of protuberances define a hollow which exceeds the size of the immunobead. Accordingly, at any given time, the immunobead makes limited contact with only a portion of the protuberances. This reduces the amount of liquid which is trapped within points of contact between the lifted immunobead and the aspiration device and reduces the amount of carry over liquid.

The preferred embodiment of the aspirator (1) is shown in FIGS. 1-4. The aspirator (1) includes a neck (2) and an inverted bowl (3). The neck (2) is connected to the inverted bowl (3) and serves to extend the inverted bowl (3) into the test tube (4), microtiter well, or other immunoassay vessel for aspirating liquid (5) therefrom and for lifting the immunobead (6). The neck (2) is hollow. The hollow portion of the neck (2) is connected at one end to the inverted bowl (3) by means of a vacuum port (7) and to the opposite end to a vacuum source (8). The vacuum port (7) enables air and liquid (5) to be drawn from the test tube (4) through said inverted bowl (3) and said neck (2) and into the vacuum source (8).

The inverted bowl (3) faces downward as the aspirator (1) is inserted into the test tube (4). The inverted bowl (3) has a concave shape. The rim (9) of the inverted bowl (3) extends nearly to the wall of the test tube (4) or other vessel. The vacuum port (7) opens onto or near the apex of the inverted bowl (3). Accordingly, when the vacuum source (8) is activated, air is drawn around the rim (9) of the inverted bowl (3) and into the vacuum port (7). As the inverted bowl (3) is lowered toward the immunobead (6), the immunobead (6) is lifted from the bottom of the test tube (4) by the vacuum and drawn into the inverted bowl (3). The immunobead (6) will remain captured within the inverted bowl (3) for as long as the vacuum source (8) is activated.



Applicant previously stated that the sidewall and ceiling of the device of Eck is formed by the same surface. In the event applicant believes the same argument is applicable to the device of Wells, the examiner asserts that applicant claim does not exclude the ceiling and sidewalls from being formed from a continuous surface or a

contiguous element. It appears as if applicant's argument was that he ceiling and sidewalls of applicant invention are separate elements. The claim does not clearly recite that the elements are separate. Applicant's figures 4 actually illustrate a ceiling and sidewalls formed from the same contiguous surface.

Elliot et al. disclose a device and method for transferring or arraying combinatorial beads. It is also desirable to separate the beads into arrays that are geometrically compatible with robotic screening systems, for example 8X12 arrays or other formats such as 384 or 896-well configurations.

A tray 24, from which the needles pick up beads, is provided on the worktable. The tray shown has four separate compartments (ampules)(shown as compartments 26, 28, 30 and 32 in FIG. 2). These compartments are spaced from one another other at intervals such that the needles 22 can enter them simultaneously.

As liquid flows into needle 22 one of the beads in the suspension, in the vicinity of the tip 52 of the needle, will ultimately be drawn against the opening at the tip of the needle. When the bead 54 closes the opening, as depicted in FIG. 5, further withdrawal of the plunger 56 of syringe 58 reduces the pressure of the air within the syringe, and line 60, and any air remaining within the pipette 16 or the needle 22. The resultant differential between the external pressure in the liquid at the tip of the needle (which is essentially atmospheric), and the internal pressure within the needle, holds the bead against the tip of the needle, so that it can be carried by the needle to one of the wells in well plate 34 (FIG. 1). The pressure decrease within the needle, which occurs when a bead is captured at the tip of the needle, is also detected by pressure sensor 70, which

delivers a signal to control 68. Signals from pressure sensors associated with all of the needles are processed by control 68, which operates the robotic manipulator 72 to move the needles from the tray 24 to the well plate 34 when beads have been captured by all of the needles that are in service.

A problem common to the prior methods is that, because the beads are extremely small, typically 300 m (0.3 mm) or smaller, there is a tendency for two or more beads, carrying different compounds, to be deposited occasionally at a single location in the array. Still another problem encountered in bead arraying is that the beads tend to be fragile, and can be broken up into fragments especially when mechanically agitated.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Wells with that of Elliott et al. to form a bead arraying system comprising a plurality of projections or transfer devices in order to provide a rapid and reliable method and apparatus for bead arraying which reliably delivers a single bead to each point in the array. Such a modification would also provide an improved apparatus for bead arraying which is inexpensive, easy to use and independent of the nature of the compounds on the beads.

8. Claims 2, 12-14, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wells in view of Elliot et al. above as applied to claim 1, in further view of Sakai *et al* (USP 4,937,048).

Wells as do not specifically recite the sidewall of each projection comprising a resiliently flexible material or the use of a suction pump. Sakai *et al* teach an elastic

(e.g. flexible) cavity, i.e. carrier holding member 217, 124 formed at a lower end region of a suction nozzle 122, 218 each of the cavities defined by a lower opening and an upper ceiling region, and a sidewall extending between the lower opening and the upper ceiling region to hold the beads 127,212 in the cavities and releasable retain them therein (Figs 11A, 13) via a suction pump 223.

Since the arm is moved up and down with respect to the reaction vessel and the carrier is removed from the reaction tube by the carrier holding member arranged at the tip portion of the arm, it is possible to remove accurately the carrier contained in the reaction vessel even if the reaction vessel has a different shape (column 7, lines 39-45 of Sakai *et al*).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing modified system of Wells flexible cavity region, as taught by Sakai *et al*, in order to allow for greater contact between the lower end region of the projection supplying the suction source and the bead, thereby lowering the chance of dropping the bead prematurely. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the sidewalls of the cavity from a flexible material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416*.

In regard to the specific diameter openings, both Wells in view of Elliot et al. and Sakai *et al* disclose the claimed invention except for the lower opening diameters and

the longitudinal length of the sidewall. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the lower opening of the cavity from between 100-1,250 micrometers and the longitudinal length of the sidewall from about 0.5-1.25 times the diameter of the lower opening, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Allowable Subject Matter

8. Claims 3, 8-10, 16, 20, 22-23, 48-54, 56-62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor fairly suggest the limitations of the claims as suggested by applicant (see arguments of supplemental appeal brief filed September 9, 2003).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gavin et al., Muscher et al., Porterfield et al., Daty et al., Velkovska et al., (,299 and ,917), Vann et al., and Schmitt et al. disclose methods and devices for transferring beads.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg

Jill Warden
Supervisory Patent Examiner
Technology Center 1700